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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,781	05/03/2001	Mitchell C. Sanders	3265.1001-000	6639
21005	7590	12/08/2003		
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133				
EXAMINER SHAHNAN SHAH, KHATOL S				
ART UNIT		PAPER NUMBER		
1645				

DATE MAILED: 12/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/848,781

Applicant(s)

SANDERS, MITCHELL C.

Examiner

Khatol S Shahnian-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-10 and 12 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Applicants' preliminary amendment C and response received 8/25/2003, paper # 19 is acknowledged.

Claims 4, 11 and 13-16 have been canceled. Claims 1 and 2 have been amended. Specification pages 13, 15, 16 and 17 have been amended.

2. Currently claims 1-3, 5-10, 11 and 12 are pending.

3. Claims 1-3, 10 and 12 are under consideration. Claims 5-9 are withdrawn from further consideration as being drawn to non-elected inventions.

#### ***Prior Citations of Title 35 Sections***

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

#### ***Prior Citations of References***

5. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 or form PTO-1449 has been submitted with this office action.

#### ***Information Disclosure Statement***

6. Applicants' Information Disclosure Statement received 8/25/2003, paper # 20 is acknowledged. The references have been considered by the Examiner. See attached PTO 1449.

#### ***Objections Withdrawn***

7. Objection to specification made in paragraph 6 of the office action mailed April 22, 2003 is withdrawn in view of applicants' amendment.

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8. Objection to drawing made in paragraph 7 of the office action mailed April 22, 2003 is withdrawn in view of applicants' submission of corrected drawings.

***Rejections Moot***

9. Rejection of claims 4, 11 and 13-16 under 35 U.S.C. 112 first-paragraph made in paragraph 8 of the office action mailed April 22, 2003 is moot in view of applicants' cancellation of those claims.

10. Rejection of claims 4, 13 and 14 35 U.S.C. 102(b) made in paragraph 9 of the office action mailed April 22, 2003 is moot in view of applicants' cancellation of those claims.

***Rejections Withdrawn***

11. Rejection of claims 1-3, 10 and 12 under 35 U.S.C. 112 first-paragraph made in paragraph 8 of the office action mailed April 22, 2003 is withdrawn in view of applicants' amendment.

12. Rejection of claims 1-3 and 10 under 35 U.S.C. 102 (b) made in paragraph 8 of the office action mailed April 22, 2003 is withdrawn in view of applicants' amendment.

***New Rejection***

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1-3, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraft, G.A. (EP 0428000A1) in view of Rambach (US 5,716,799) and further in view of Vollmer et al. (Infection and Immunity, Vol.64, No.9, 1996). Prior art of the record, applicant's 1449

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The claims are drawn to a method of detecting presence of a pathogenic microorganism (*Listeria monocytogenes*) in a sample, the method comprising the steps of:

- contacting a test sample with a substrate specific for a protease that is unique to the organism; and
- detecting cleavage of the substrate.

Kraft, G.A. teaches a method of detecting presence of a pathogenic microorganism in a sample, the method comprising the steps of:

- contacting a test sample with a substrate specific for a protease that is unique to the organism; and
- detecting cleavage of the substrate.

see pages 2, 3 and examples 2 and 3. Kraft, G.A. also teaches measuring this activity using a quenched label. Kraft, G.A. teaches detecting the presence of pathogenic microorganism such as human immunodeficiency virus and avian myeloblastosis virus. (see page 3). Kraft, G.A. does not teach bacterial pathogen *Listeria*. However, Rambach teaches a method for detecting the presence or absence of *Listeria* in a sample by using an enzyme substrate chromogen (see abstract, column 3 and claims specially claim 14). Rambach does not explicitly teach metalloprotease. However Vollemer et al. teach detection of metalloprotease of *Listeria monocytogenes* in samples (culture supernatants) see abstract, pages 3646, 3647 and 3649.

It would have been prima facie obvious to one of ordinary skill in the art to combine the methods taught by Kraft, Rambach and Vollemer et al. to obtain the claimed invention. One of ordinary skill in the art would have been motivated by the teaching of Kraft that the concept of his invention can be appreciated by one skilled in the art the use of fluorogenic substrates in other

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assay procedures (see page 12 Kraft).

*Conclusion*

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

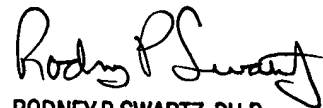
Khatol Shahnan-Shah, BS, Pharm, MS



Biotechnology Patent Examiner

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November 30, 2003



RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER